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SUBJECT: FDA CHIEF EXPECTS NO MORE CL'S

¶1. Summary: Dr. Siriwat Tiptaradol, Secretary General of the Thai Food and Drug Administration (FDA), said he expected no new compulsory licenses on drugs, crediting progress in recent discussions with European pharmaceutical companies on pricing and access for four cancer drugs. However, the companies say discussions thus far have been preliminary and have not offered any concessions. Ongoing discussions with three companies hit by compulsory licenses in the last year have not progressed and the Government Pharmaceutical Organization is moving forward with plans to import a generic copy of HIV drug Aluvia, nine months after announcing a compulsory license. Thai political parties are vague on what position they will hold on the issue after December elections. End Summary.

¶2. In a courtesy call by Econ Counselor and Econoff on October 25, Dr. Siriwat said he thought there "shouldn't have to be more compulsory licenses," but emphasized this was his personal opinion and he could not speak for the Ministry of Public Health. The Ministry is considering breaking patents on four cancer drugs distributed by three European companies, following on the issuance of compulsory licenses on two HIV/AIDS medicines and a heart drug over the last year. The four cancer drugs are distributed by Swiss-owned Novartis and Roche, and French-owned Sanofi-Aventis. Dr. Siriwat said initial discussions beginning October 18 had gone well and companies had responded positively, particularly Roche. Siriwat explained the Ministry's long-held position that Thailand's public health system was unable to cover the costs for expensive life-saving drugs and compulsory licenses were necessary to widen access. He assured that generic versions would be provided only to the poor under the RTG's universal health care program. Dr. Siriwat claimed the Thai program "will actually expand the companies' market in Thailand," as those who can afford the drugs, such as patrons of private hospitals and those with commercial health insurance, will still pay the current prices.

¶3. Dr. Rolf Ammelburg, Managing Director of Roche Thailand, said his initial meeting with the FDA had gone well; the company showed its openness to discussion and new proposals, but made no commitments. Ammelburg said the FDA had proposed that Roche lower the price of their lung cancer drug erlotinib, submit to a voluntary license, or face the possibility of a compulsory license. The FDA did not clearly define how a voluntary license would operate, but Ammelburg assumed that the FDA aimed to pursue domestic production under license from Roche. He noted, however, that Thailand may not have the domestic capability to produce the drug. Thailand had announced two years ago it would begin generic manufacture of another Roche drug, Tamiflu, but has yet to produce a single capsule. Ammelburg felt that the FDA was not anxious to do a compulsory license and was strongly pushing the other options to avoid such a result.

¶4. There has been no further progress in discussions with Merck or Abbott, whose patents on antiretrovirals were broken in November 2006 and January 2007, respectively. The FDA announced October 17

that it had approved the registration of a generic version of Aluvia, a new heat-stable form of Abbott's AIDS drug Kaletra. The Government Pharmaceutical Organization (GPO) said it would soon begin importing the drug from Indian generic manufacturer Matrix Laboratories, enough for 8000 HIV-positive patients for six months. Matrix offered a price of USD 695 per patient per year, about three hundred dollars less than Abbott's listed price.

15. The FDA appears to have taken a questionable shortcut to approve the generic version of Aluvia. When Thailand issued a compulsory license on Kaletra, the older version of the antiretroviral, Abbott retaliated by pulling the registration paperwork for the new version, Aluvia, which was then only months away from approval. Thailand has decided to import generic Aluvia, though its compulsory license is actually on Kaletra. Both drugs share the same chemical combination, lopinavir/ritonavir, but it is unclear if the compulsory license on the older drug would allow importation of a generic version of the new drug. As well, safety and efficacy data required for approval is not on file for Aluvia, and FDA officials say they simply accepted the data for Kaletra in its absence. The FDA added a condition to the drug registration that a sample of patients would be tested after six months to determine if the generic version was effective.

Abbott in the dock

16. The Thailand Competition Commission is reviewing a complaint local public health NGOs have brought against Abbott for its decision earlier this March to withdraw the pending registrations of seven new drugs, including Aluvia. The complaint alleges that Abbott's action contravenes Section 28 of Thailand's Competition Act which forbids restricting opportunities for consumers "to purchase goods or services directly from business operators outside the

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Kingdom." The Commission is still gathering information about the case and has asked Abbott for market share and cost data. If the Commission concludes that Abbott made anti-competitive practices, they can recommend the case to a court for a fine or possible criminal charges. Abbott's lawyers say the case probably would not meet the Competition Act's criteria for market dominance for anti-competitive practices, but are nevertheless concerned that local Thai management could be brought up on criminal charges.

Politics isn't over

17. Political parties vying for election this December are hedging on policies on compulsory licenses they might follow if elected. In a forum on access to medicine hosted by public health NGOs, Mr. Buranaj Smutharaks, representing the Democrat Party, said his party would not obstruct the compulsory licensing process. Party leader Abhisit Vejjajiva had earlier delivered a pro-business message on the issue to a business and investor audience, saying he would work with the pharmaceutical industry and would use compulsory licenses only as a last resort. However, Buranaj told the health forum that "it is highly possible the last resort will get the first priority." Representatives from the People Power Party and Chart Thai party told the forum they supported the decision to adopt compulsory licenses, but could not commit to how their parties would pursue the issue as part of a likely coalition government.

18. Comment: Less than two months remain until national elections and a thorough change in government, but this is ample time in which to implement more compulsory licenses. Despite Dr. Siriwat's view that no more will be necessary, the final decision will be made by the Minister of Public Health who may yet use his last days in office to push through a last-minute bid for more CLs. Post-election, much of the Ministry's top staff will turn over and there may be few opportunities in the future to pursue this policy. The leading political parties have paid lip service to the current policy, but for the most part they are pro-business and would be unlikely to pursue compulsory licenses as aggressively as has the current government. End Comment.